February 6, 2015

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National Coordinator
Office of the National Coordinator for Health IT/Office of the Secretary
Department of Health and Human Services

RE: Federal Health Information Technology (IT) Strategic Plan 2015-2020

Dr. DeSalvo,

The Heart Rhythm Society (HRS) appreciates the opportunity to provide written comments in response to the *Federal Health IT Strategic Plan (2015-2020)*. HRS represents more than 5,600 heart rhythm specialists, including physicians, scientists, and allied professionals, who perform electrophysiology (EP) study studies, pacemaker implants, ICD implants, and curative catheter ablation to diagnose, treat and prevent cardiac arrhythmias.

We applaud ONC for collaborating with its federal partners to set forth an actionable strategy that would improve health, health outcomes, and potentially reduce healthcare spending, through streamlined information exchange among relevant stakeholders. In the paragraphs below, we raise concerns specific to the identified goals of collecting, sharing and using health IT, coupled with thoughtful comments and actionable solutions to addressing those issues. We look forward to a meaningful dialogue with ONC on this and related efforts.

Federal Health IT Goals

Expand Adoption of Health IT

For ONC to achieve its goal of expanding the adoption of Health IT, we believe significant modifications to the EHR Incentive Program and Certification Criteria must be made.

First, HRS believes that the development of data and interoperability standards followed by adoption of such standards is a critical first step. Data and interoperability standards are required for development of a health IT infrastructure that can support the ultimate goal of the HITECH Act, which is "to use health IT to create measurable improvements in population health through a transformed health care delivery system." Since 2005, the HRS has partnered with industry and *Integrating the Healthcare Enterprise* (IHE) to identify areas of clinical practice where gaps limit clinicians' abilities to provide optimal care. Working with industry engineers under the construct of IHE, HRS has developed standards-based solutions to these clinical gaps in care in order to provide industry with the leadership and guidance to implement such solutions.

We continue to actively develop several IHE interoperability profiles under the Cardiology and Patient Care Devices Domains. For example, the Implantable Device Cardiac Observation (IDCO) profile specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemakers (PMs), implantable defibrillators (ICDs), and cardiac resynchronization

therapy device (CRT) interrogations (observations) or messages. This profile was developed by HRS in partnership with cardiac rhythm management industry (all vendors represented), tested, validated, and certified by the IHE's rigorous standards development process. Although the IDCO profile was developed in partnership with industry, we have been unsuccessful in convincing industry to implement the full IDCO profile in their market release products. In turn, this has limited our ability to seek adoption and implementation by the electronic health record industry and personal health record vendors. It also has limited our ability to encourage utilization of the interoperability profile for data registries, quality monitoring, and post-market approval U.S. Food and Drug Administration (FDA) surveillance studies.

This serves as an example that development of the standard is a critical *first* step, but the process doesn't end there. Gaining momentum to achieve sufficient adoption and implementation requires further partnerships, including with federal agencies. We discuss HRS-led efforts to address interoperability below.

Second, we are concerned about the usability of current EHR products – including certified EHR technology (CEHRT) – and the impact of usability on patient safety and quality. We note that ONC has recognized this issue, but we are not convinced that enough is being done to address our concerns. Therefore, we urge ONC to mandate vendor adherence to usability standards. In addition, accredited testing bodies should conduct human factors usability testing in a multitude of healthcare situations and clinical scenarios, including a variety of electrophysiology laboratory environments.

Similarly, we urge ONC to work with CMS to update the Quality Assessment and Performance Improvement (QAPI) Condition of Participation to require hospitals and other facilities to include their medical staffs in health IT purchasing decisions and implementation processes, as well as establish a process that would facilitate reporting of patient safety issues associated with EHR use and timely responses to medical staff concerns about patient safety and other health IT issues during and after implementation.

Finally, CMS and ONC, working in collaboration with medical specialty societies, including HRS, must gather robust data regarding physician practices' experience with implementation under the EHR Incentive Program, and the associated meaningful use (MU) criteria. This is particularly important now that the EHR Incentive Program has moved to a penalty-only phase, with few hardship exceptions to help practices avoid penalties when they are unable to adopt health IT due to formidable circumstances.

From our perspective, there remains a paucity of evidence regarding the feasibility of MU Stage 1 and Stage 2 criteria and the effect of those criteria on physician practice and overall patient care and safety. In addition, there are still widespread gaps in certified EHR technology functionality. Given that investment in an EHR system requires a considerable amount of time and financial resources, this is evidence we must have and analyze prior to the launch of MU Stage 3, which will be released in draft form in the weeks ahead.

Advance Secure and Interoperable Health Information

HRS recently convened a group clinicians, federal agency staff, private sector experts, CRM device manufacturers, EHR vendors and accrediting organizations, to draft a health policy statement and white paper which will give guidance to stakeholders regarding implementation of structured reporting and interoperability data standards specific to EP clinical workflow.

The health policy statement will serve as the formal means to promote the concept of structured reporting for EP, data dictionaries, interoperability standards and will outline sample structured reports for AF ablation and for longitudinal management of patients with ICDs. Additional structured reports will be added over the upcoming years. The white paper will give technical guidance to industry, regulatory and accreditation agencies for implementation of the structured reports presented in the health policy statement. Both documents are expected to be released in 2015.

However, and despite recognition by many engineers working in the CRM and EHR space that the IDCO profile is an important step toward interoperability, EP demand for such functionality is not always enough to prompt adoption. EHR vendors tell us they face financial pressures and can only expend finite resources based on a strong business case. For finance executives within EHR vendor companies to authorize funding to incorporate the profile, we believe the profile needs to be recognized by the ONC in the certification criteria, as it is our understanding that the "business care" comes down to the federal requirements set forth in the certification criteria. Therefore, we maintain that recognition of the full IHE IDCO profile in the certification criteria would go a long way toward helping EHR vendors strengthen the business case for incorporating the profile into their respective systems.

In light of the aforementioned, and our belief that standards are the foundational step toward robust interoperability, we urge ONC to revise the order of its Goal 2 objectives as follows:

- New Objective 2A: "Identify, prioritize, and advance technical standards to support secure and interoperable health information"
- New Objective 2B: "Enable individuals, providers, and public health entities to securely send, receive, find, and us electronic health information"

Finally, our efforts to adopt and promote clinical data registries have led to some important discoveries. This would only be furthered with secure interoperable data exchange for clinical platforms, data registries, and applications. We urge ONC to add an additional objective that would facilitate this activity.

Advance the Health and Well-Being of Individuals and Communities

ONC previously proposed to incorporate the FDA's Unique Device Identifier (UDI) into the certification criteria for certified electronic health record technology (CEHRT). This, too, is an important step to improving patient safety.

HRS anticipates that future certification criteria would promote functionality that would assist providers in recording and reporting adverse event information associated with implantable devices electronically to manufacturers and FDA through CEHRT. However, beyond inclusion of the UDI as a certification criterion, HRS strongly urges the ONC to incorporate other important functionality requirements that will allow EPs to remotely monitor patients with implantable pacemakers and defibrillators.

We discussed above our collaborative efforts to address interoperability and remote monitoring, but would like to remind ONC of the benefits of the IDCO profile to achieving this aforementioned federal health IT goal

- Standards based translation and transfer of summary device interrogation information, and
- Improved workflow efficiencies in Cardiology and Electrophysiology practices from management of "key" summary implantable rhythm control device interrogation information in a central system such as an EHR or a device clinic management system.

Data could also be collected and incorporated into a clinical data registry devoted to improving care for this subset of patients, which aligns with the Federal Health IT Goal, "Strengthen Health Care Delivery" and its associated objectives.

Beyond the aforementioned benefits of the IDCO profile, HRS maintains that such functionality will help EPs better engage patients in their heart rhythm care which is also key to improving outcomes. Improved patient engagement through use of the IDCO profile is evidenced by results from a 2011 ONC Challenge Grant on Consumer-Mediated Information Exchange, whereby a group of key stakeholders in Indiana delivered data to patients' personal health records (PHRs) through remote monitoring of their implantable cardioverter-defibrillators (ICDs). Major outcomes of the Challenge Grant project were reduced time between cardiac events and clinician review of the data, which improved patient outcomes, and reduced emergency room and office visits by patients with ICDs.

We also believe the collection of this data would be useful toward helping EPs develop clinical decision support metrics based on data received from implanted devices, prompting earlier intervention if or when problems arise. Incorporating the IHE IDCO profile into the certification criteria supports the federal governments broader effort to ensuring patients receive the right care, at the right time.

ONC has included proposals in draft rulemakings that would incorporate other IHE profiles, therefore, we surmise that the agency recognizes the value these consensus driven profiles to increasing interoperability.

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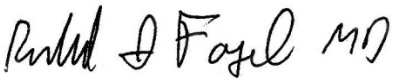
Thank you for your leadership on this important issue. We look forward to working with CMS staff on these issues. If you have questions about these public comments or would like additional information about HRS activities, please contact Isabelle LeBlanc, HRS's Manager of Health Policy, at ileblanc@hrsonline.org.

Sincerely,



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